

REMARKS

This responds to the Final Office Action mailed on 28 January 2009. Applicants request reconsideration of the application in view of the following remarks. Claims 35-39, 41, 42, 44-49, 51-55, 57-71, 73, 76 and 77 are pending in the application. Of the pending claims, claims 35, 37, 44, 49, 55, 63, 67 and 71 are independent.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 35-39, 41, 42, 55 and 57-62 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,662,681 to Nash et al. in view of U.S. Published Application No. 2001/00024402 to Bonutti (Bonutti '402) and U.S. Patent No. 5,814,073 to Bonutti (Bonutti '073). Applicants respectfully traverse this rejection.

Claims 35 and 37 recite a multi-level nest in a carrier tube that includes “a first surface contacting the anchor; a second surface spaced from the anchor in a direction radially inward relative to the first surface when the anchor is in an undeployed position; wherein the first and second surface are part of an outer surface of the carrier tube.” Claim 35 further recites “deploying the anchor into the tissue puncture by . . . inserting a portion of the insertion sheath between the anchor and at least one of the first and second surfaces of the multi-level nest to rotate the anchor into a deployed position.” Claim 37 also recites “inserting at least a portion of the insertion sheath into the gap [created by the multilevel nest] to rotate the anchor into a deployed position.” Claim 55 recites “the carrier tube including an outer surface, the outer surface including a first surface portion that is in contact with the anchor in a recess positioned adjacent to the anchor, the recess extending radially further into the outer surface of the carrier

tube than the first surface portion; and inserting at least a portion of the insertion sheath into the recess to rotate the anchor.”

Nash discloses a closure device 20 that includes a sealing member 30, an anchor member 32, a positioning filament 34, and a locking member 36. The closure device 20 is part of an instrument 100 for closing and sealing an opening. The instrument 100 includes a tubular carrier 102, a bypass tube 104 and a tamping member 106. Carrier tube 102 has a construction at its distal end such that the anchor 32 is disposed longitudinally within the bypass tube 102 and adjacent to the carrier tube in a lateral direction prior to the anchor being deployed. FIG. 1 of Nash shows a proximal portion of the anchor member 32 in direct contact with the exterior/side surface of the carrier tube 102. There is no space or gap defined between the anchor member 32 and the carrier tube 102 when the anchor is in the undeployed position shown in FIG. 1.

Nash further discloses positioning the sealing plug 30 and locking member 36 within the carrier 102. The filament 34 is coupled to the anchor 32 and then passes into the carrier 102 where it is coupled to the sealing plug 30 and locking member 36 before extending further in a proximal direction within the carrier 102. Positioning the filament 34 within the carrier 102 is an important aspect of the Nash device in that it provides a connection between the anchor, which is positioned outside of the carrier tube 102, and the sealing plug 30 and locking member 36, which are positioned internal of the carrier tube 102 and must be discharged out of the distal open end of the carrier tube 102.

In contrast, Bonutti '440 discloses a device in which the suture 32 is positioned and maintained external of the cylindrical inner member 92 (what the Examiner has identified as “a carrier tube”). The inner member 92 includes a small slot 106 that extends in a longitudinal

direction along an outer surface of the inner member 92 for passage of the suture 32 between an anchor member 30 and an outer surface of the inner member 92. The slot 106 disclosed by Bonutti '440 has a much different purpose and function than those features of Nash described above and the features of claims 35, 37 and 55 recited above. In fact, providing a slot feature along an outer surface of a carrier tube for passage of a suture actually teaches away from the limitation of the claims 35, 37 and 39. One of skill in the art reviewing the disclosure of Nash, which discloses an arrangement in which the carrier tube is hollow and the filament extends internal of the carrier tube, would have no motivation to modify the Nash device to include a separate path for the filament along an exterior surface of the carrier tube. Because of the significant differences in structure and function between Nash and Bonutti '440, there is no motivation to combine the teachings of Nash with the teachings of Bonutti '440.

Further to the above, the teachings of Bonutti '440 and Bonutti '073 teach away from the use of an insertion sheath to manipulate a position of an anchor. In each of Bonutti '440 and Bonutti '073, an anchor is advanced distally into position within a tissue layer and oriented within that tissue layer with a structure that is separate from an insertion sheath. In the case of Bonutti '440, the anchor is carried to a position within the tissue layer on an inner member 92 and then advanced off of the inner member 92 using an outer member 94 that engages a proximal end surface of the anchor 30. In Bonutti '073, a tubular inner member 54 pushes the anchor 22 through an open leading end portion 62 of the tubular outer member 30 (a sheath-like member). Bonutti '073 describes at column 7, lines 25-53 that the inner member 54 is advanced distally until it extends out of the open leading end portion 62 of the tubular outer member 30 and can be operated in that fully extended position to manipulate a position of the anchor within the tissue

layer. There is no disclosure or suggestion by Bonutti '073 of using the tubular outer member 30 to engage or contact the anchor 22 in anyway, except along outer side surfaces of the anchor 22 as the anchor 22 is pushed through the open leading end of 62.

In view of the very limited operation of the devices disclosed by Bonutti '440 and '073 (in particular the tubular outer member 30 in Bonutti '073), one of skill in the art reviewing Bonutti '440 and Bonutti '073 would not be motivated to combine the teachings of those references with the teachings of Nash.

Furthermore, even combining the teachings of Bonutti '073 with the teachings of Nash fails to disclose or suggest “inserting a portion of the insertion sheath between the anchor and at least one of the first and second surfaces of the multilevel nest to rotate the anchor into a deployed position,” as required by claim 35, “inserting at least a portion of the insertion sheath into the gap to rotate the anchor into a deployed position,” as required by claim 37, or “inserting at least a portion of the insertion sheath into the recess to rotate the anchor,” as required by claim 55. The mere disclosure of resilient tips on the tubular outer member 30 of Bonutti '440, which resilient tips are provided in part to limit return movement of the anchor back into the tubular outer member 30, is not a disclosure of the claimed method step of inserting a portion of the insertion sheath between the anchor and the recess surface of the carrier tube, as recited in claims 35, 37 and 55.

In view of the above, applicant submits that Nash, Bonutti '440 and Bonutti '073 fail to disclose or render obvious every limitation of claims 35, 37 and 55, and the claims that depend from them.

Claims 44-49, 51-54, 63-66, 71, 73, 76 and 77 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nash in view of Bonutti '073. Applicants respectfully traverse this rejection.

Claim 44 recites “the carrier tube including an outer surface, the outer surface including a first surface portion that is in contact with the anchor and a second surface portion that is adjacent to the anchor and recessed in the carrier tube relative to the first surface portion; and inserting at least a portion of the insertion sheath between the anchor and at least one of the first and second surface portions to rotate the anchor.” Claim 63 recites “deploying the anchor by moving a tip of the insertion sheath into a recess in an outer surface of the carrier tube so that the tip is underneath the anchor before the anchor begins to move from an undeployed position, and distally advancing the insertion sheath in the recess rotates the anchor into a deployed position. Claim 71 recites “carrier tube including a recess in an outer surface of the carrier tube, the recess extending underneath the anchor; and positioning a tip of the insertion sheath in the recess so that the tip is between the carrier tube and the anchor before the anchor begins to move from an undeployed position, and distally advancing the insertion sheath in the recess rotates the anchor into a deployed position.”

Nash and Bonutti '073 fail to disclose or render obvious every limitation of independent claims 44, 63 and 71 for at least those reasons discussed above related to independent claims 35, 37 and 55. Neither Nash nor Bonutti '073 discloses or suggests “a second surface portion that is adjacent to the anchor and recessed in the carrier tube relative to the first surface portion,” as required by claim 41, “a recess in an outer surface of the carrier tube . . . before the anchor begins to move from an undeployed position,” as required by claim 63, or “a recess in an outer

surface of the carrier tube, the recess extending underneath the anchor,” as required by claim 71. The anchor member disclosed by Nash is maintained in direct contact with an outer surface of the carrier tube with no gap or space defined therebetween while the anchor is an undeployed position shown in FIG. 1.

Bonutti '073 also clearly fails to disclose or suggest a space or recess defined between the anchor 22 and an outer surface of the tubular inner member 54 into which a portion of the tubular outer member 30 is inserted or advanced. Therefore, Nash, alone or in combination with Bonutti '073 fails to disclose or render obvious every limitation of at least claims 44, 63 and 71, and the claims that depend from them.

Further to the above, the Examiner contends at page 4 of the Office Action that because Bonutti '073 discloses a sheath-like member having resilient tips that prevent the anchor from accidentally passing back into the introducer sheath it would be obvious to one of ordinary skill to “use an introducer sheath with resilient tips as taught by Bonutti '073 with the closure device of Nash referenced to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.” The Examiner has not addressed the specific limitations of claims 44, 63 and 71 related to the inserting, moving, or positioning of the insertion sheath in a gap or space defined between the anchor and a recessed portion of the carrier tube. Therefore, the Examiner has failed to set forth a prima facie case of obviousness.

Claims 67-70 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 5,282,827 to Kensey et al. in view of Bonutti '073. Applicants respectfully traverse this rejection.

Claims 67 recites “the anchor including an indentation that forms a gap between the anchor and a carrier tube, the gap being open along a proximal edge of the anchor; positioning a tip of the insertion sheath in the gap before the anchor begins to move from an undeployed position, wherein distally advancing the insertion sheath in the gap rotates the anchor into a deployed position.”

Kensey discloses with reference to FIGS. 34 and 35 an alternative anchor member 32' that includes means to enable it to be imaged radiographically. The anchor member of 32' includes a pair of wells 32A on the top surface 48. A plug or powder of a conventional radiopaque material is located within each well 32A. A respective cover or cap 32B is secured to the top surface 48 to the anchor 32' by a seal line extending about the periphery of the well. The wells 32A are spaced inward from peripheral edges of the anchor 32'. The wells 32A are not “open along a proximal edge of the anchor,” as required by claim 67 or constructed in any manner in which it would be possible for a tip of an insertion sheath to be inserted into the wells 32A before the anchor begins to move from an undeployed position (*i.e.*, see FIG. 11 of Kensey) to a deployed position. Therefore, Kensey fails to disclose both the claimed “gap” feature relative to the indentation in the anchor and the step of “positioning a tip of the insertion sheath in the gap,” that are required by claim 67. Bonutti '073 fails to remedy the deficiencies of Kensey as it relates to claim 67.

Bonutti '073 is cited merely for its teaching of a sheath-like member (*i.e.*, a tubular outer member 30) that includes resilient tips. However, there is no teaching or suggestion by Bonutti '073 of inserting the resilient tips into a gap defined between an anchor and a carrier tube “before the anchor begins to move from an undeployed position,” as required by claim 67.

Further to the above, the Examiner contends at page 5 of the Office Action that “the anchor is indented because of the area between the raised cap portion of 32B and the proximal end of the anchor. The indent will cause a gap between the anchor and the carrier tube.” Applicants respectfully disagree with this interpretation of the Kensey device. The gaps 32B are separate pieces that are mounted to the anchor merely for the purpose of sealing closed the wells 32A. The only portions of the anchor 32' that are indented are the wells 32A. However, as discussed above, the wells 32A are not opened along a proximal edge of the anchor and are not available for “positioning a tip of the insertion sheath in the gap before the anchor begins to move from an undeployed position,” as required by claim 67. At best, the caps 32B are spacers between the anchor and carrier tube, but are not “indentations” or in any way configured to define “an indentation of the anchor.” Therefore, Applicant submits that Kensey fails to disclose or suggest every limitation of claim 67, alone or in combination with Bonutti '073 for this additional reason.

Conclusion

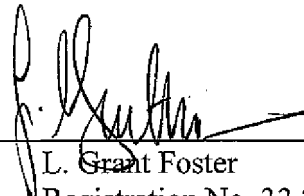
For at least the foregoing reasons, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicant invites the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Applicants expressly disclaim all arguments, representations, and/or amendments presented or contained in any other patent or patent application, including any patents or patent

applications claimed for priority purposes by the present application or any patents or patent applications that claim priority to this patent application. Moreover, all arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

Respectfully submitted,

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